

GUEST EDITORIAL

Image-Guided Breast Biopsy—How, When, and by Whom?

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Despite some recent confusion regarding the optimal age to begin mammographic screening, increasing numbers of women in the United States are taking advantage of this technique for early detection. Early press reports on the developing federal budget “deal” indicate that even Medicare may soon cover yearly mammograms. Relative to the goal of reducing breast cancer mortality, this is good news indeed. Along with this rise in screening examinations, however, has come a steady rise in the need for biopsies to diagnose some of the abnormalities found. Each year between half a million and one million women and their physicians will be faced with a decision about how best to establish the nature of an abnormality found on mammography [1,2]. And, more than ever, this decision must include consideration of costs and efficiency as well. Until relatively recently, this choice was fairly simple: one either followed an abnormality with a repeat mammogram in 6 months or proceeded directly to mammographically guided needle localization and surgical biopsy.

For many years, we have depended on needle biopsies, either fine needle aspirates (FNA) or core needle biopsies, as the most efficient way to establish the diagnosis of *palpable* breast masses. It is clear that this technique, although not error-proof, can greatly facilitate the management of breast cancers while eliminating one surgical procedure performed solely for diagnosis. This is particularly advantageous for women who choose breast conservation after the diagnosis of cancer is made. Although needle biopsy has a high degree of accuracy in experienced hands, there is a finite false-negative rate, and it has generally been the standard of care to biopsy surgically any palpable breast mass if a malignant diagnosis is not returned on FNA. As we will see, a different standard is often applied to needle biopsies of occult nonpalpable lesions.

During the past few years, new technology that makes it feasible to obtain needle biopsies under mammo-

graphic guidance has been popularized in the United States. As is the case for palpable cancers, this may eliminate one surgical procedure for occult cancers; for benign lesions, surgery may be avoided altogether. A number of different types of equipment are marketed for stereotactic breast biopsy (SBB) procedures, performed with the patient either upright or in the prone position. The high accuracy rate of this technique has been established in a number of published series [3-8]. As with FNA and core needle biopsy for palpable masses, the false-positive rates are extremely low. The false-negative rates are also quite low in most series, although these have sometimes been compared with false-negative rates for the surgical approach that are absurdly high. With careful technique, the latter should be about 1% or less. Accepting a follow-up rather than an intervention strategy for negative stereotactic biopsies of occult lesions hinges on the fact that the targeting is generally quite accurate, and even if the lesion is malignant, a nonpalpable cancer missed by needle biopsy is still very early in its course. Core needle biopsy, moreover, actually provides a piece of tissue for histopathology. As with the accepted need to proceed to surgical biopsy for definite palpable masses, if the needle biopsy is negative, most groups require surgical biopsy for occult lesions if the SBB result and the radiographic appearance in terms of “risk” are discordant [3,8]. Without arguing the accuracy of this technique, a number of controversial issues have arisen about when to use SBB or some other technique and by whom it should be performed.

Perhaps the most advantageous use for SBB is to establish the diagnosis of mammographic abnormalities that are of low to moderate suspicion for malignancy [7]. These are lesions that would have required surgical bi-

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opsy previously but have only 10 to 20% likelihood of being cancer. If the histologic diagnosis matches the radiologist's predicted diagnosis, then these patients, it seems, can safely be followed up and have been saved the morbidity and expense of surgery. However, as some radiologists become overly suspicious, cautious, or aggressive and as patients become aware of the technique, recommendations for SBB are being made for lesions that are only minimally suspicious or almost certainly benign. These are findings for which no one would have recommended a surgical biopsy in the "pre-SBB" era, and most should not have an SBB performed now. They can be managed quite safely, and at much lower cost, by careful follow-up with an early interval (usually 6 months) mammogram to assess stability of the radiologic findings. In fact, for many patients seen in our center after a recommendation for SBB or surgical biopsy elsewhere, all that is really needed is comparison to previous films, an ultrasound, or magnification views to be able to reassure the patient that the finding is almost certainly benign. Other groups have found also that a high proportion of patients referred for biopsy actually did not need one [2,9,10]. Mammographic follow-up is certainly less invasive and less costly than an SBB. It is clear that SBB is less costly than surgical excision, but these cost savings will be quickly wiped out if many additional unnecessary biopsies are performed as a result of increased availability of SBB and the loss of the deterrent value of surgery.

At the other extreme, we often see patients for whom an SBB has either been recommended or actually performed after a mammogram on a patient with a mass that is easily *palpable*. We have seen women who have had SBB despite large palpable axillary nodes or a palpable breast mass in excess of 3 cm in diameter. Obviously, these lesions are much more simply and cheaply diagnosed by FNA using digital (meaning by fingers!) guidance. Often, such unnecessary SBB procedures are recommended to family physicians, primary care internists, or gynecologists who have little basis for choosing one approach over another and who may not have examined the patient recently. They (and their patients) are essentially at the mercy of the radiologist for a decision as to how to proceed when this is the case. These occasional excesses in the use of SBB illustrate the need for good communication among clinicians and radiologists. Fortunately, most radiologists have sound training and a sensible approach to issues regarding the optimal approach to diagnosis. Moreover, in dedicated mammography centers, the radiologist will often examine the patient having a mammogram, especially if it is a diagnostic study indicated for a clinical problem. Another way to ensure that patients do not undergo inappropriate SBB is to have decisions made jointly by radiologists and breast surgeons after referral to a multidisciplinary breast center.

This also relates to the "hot" question as to who should be performing these procedures. This issue will be discussed later.

Whereas SBB is an ideal approach for low to medium suspicion mammographic abnormalities (either masses or calcifications), some patients with other types of abnormalities may still be better served by the "old fashioned" needle localization and open surgical biopsy. Perhaps the best question to ask when making this choice is whether the SBB is likely to reduce or increase the total number of procedures the patient will undergo (and the costs involved). For example, for an elderly woman with a small, highly suspicious mass, a single procedure to remove the lesion completely after needle localization is likely to be the only surgical procedure required. A positive SBB to establish the diagnosis will only add an extra step and additional expense. In fact, for such a high-suspicion lesion, we would be unlikely to accept a negative SBB result, and a surgical biopsy would be performed anyway. For a younger patient, however, establishing the diagnosis by SBB may allow one to proceed directly to definitive excision and axillary node dissection. In this scenario, SBB does not reduce the total number of procedures, but it does reduce the number of *surgical* procedures and the costs incurred. It has also been argued that definitive excision of a cancer is more effectively performed after SBB, with a greater likelihood of negative margins [11]. However, the same pathologic result can be accomplished by wide excision of highly suspicious lesions at the time of surgical biopsy. This has been our standard policy; similar to published results, negative margins are achieved in the vast majority of cases [12]. Most patients then need only an axillary node dissection (AND) to complete their surgical treatment. Some, such as those with ductal carcinoma in situ (DCIS) or elderly patients, need no further surgery, thus completing diagnosis and definitive surgery in a single step. For the few patients who undergo definitive "lumpectomy" for a presumed cancer and in whom margins are positive on the initial specimen, reexcision of the primary site can be performed at the time of AND. Despite this, the total number of procedures for these patients is still only two. Even for palpable prediagnosed cancers, it occasionally takes two "tries" to achieve negative margins. Often, it is argued that SBB saves the patient an extra anesthetic. Because almost all surgical breast biopsies, including definitive excision after needle localization, can be performed with local anesthesia, this point is relatively moot.

Another difficult area is what to do about the patient with highly suspicious calcifications. First, core needle biopsy, not FNA, should be performed for calcifications, and the specimens should be examined radiographically for the presence of the calcifications. Moreover, removal of all of the calcifications by SBB should be avoided,

TABLE I. Recommended Approaches to Occult Mammographic Breast Abnormalities*

Abnormality	Recommended approach	Comments
Minimally suspicious	Follow-up mammogram, no biopsy	Minimal risk and cost effective; only risk is rare delayed cancer diagnosis
Low to moderately suspicious mass	SBB or ultrasound-guided core biopsy	Later surgery unlikely to be necessary
Low to moderately suspicious calcifications	SBB	Calcifications should be in biopsy specimen but some must remain in breast; if calcifications not in specimen and targeting was good, can obtain early repeat mammogram
Architectural distortion	NL and surgical biopsy	SBB may lead to false positives
Highly suspicious mass	NL and surgical biopsy (generally preferred) or SBB	Choice depends on patient characteristics, size of lesion, likely choice of breast conservation versus mastectomy, etc.
Highly suspicious calcifications (localized)	NL and surgical biopsy	Will probably limit number of procedures (1 or 2 vs. 2 or 3 with SBB first)
Highly suspicious calcifications (diffuse)	SBB	Minimize biopsy procedures in probable mastectomy candidate
Additional lesions in patients being considered for breast conservation (for established cancer)	SBB	Helps define ideal definitive treatment option

*SBB, stereotactic breast biopsy; NL, needle localization.

because this may make it difficult to find the lesion for later definitive excision if this is indicated. If a core SBB establishes a diagnosis of ductal carcinoma in situ, the next step will be definitive excision after needle localization. Then, if pathologic examination of the definitive breast specimen reveals invasive cancer (which may occur in 15 to 20% of such lesions), a third procedure will be required to assess the axillary nodes [3,13]. If definitive excision after mammographic needle localization, rather than SBB, was performed as the first procedure, this would *reduce* the number of total procedures by one. Of course, if malignant appearing calcifications are spread diffusely in the breast, than a mastectomy may be necessary, and SBB is particularly helpful in this less-frequent circumstance. Likewise, in a patient with a diagnosed cancer, SBB of additional suspicious abnormalities may be extremely valuable in choosing the most appropriate local treatment option.

Summarized in Table I are what we consider to be the ideal clinical presentations for use of SBB and those that are probably better suited for surgical excision. Table II outlines some of the contraindications for the SBB approach. For architectural distortion, SBB is contraindicated, because core needle biopsy of a radial scar can lead to false-positive diagnoses. In most cases, the optimal choice can best be made after surgeon and radiologist confer and the pros and cons of both approaches are then discussed frankly with the patient. Some patients, for example, will only feel reassured by removal of the mass in question. Interestingly, despite the marketing that offers patients a biopsy without surgery, a surprisingly high proportion of patients who have had both procedures say that they would choose surgery over SBB the

TABLE II. Contraindications to Stereotactic Breast Biopsy

Contraindications	Comments
Minimally suspicious lesion	Follow-up mammogram preferred
Palpable lesions	"Digitally" guided biopsy preferred
Architectural distortion	May lead to false positives if radial scar
Breast compresses too thin	Does not allow for needle "throw"
Patient cannot lie prone	May still be able to do SBB on upright unit
Patient preference	Some patients prefer to have lesion removed

next time, based on considerations of comfort and time spent.

One of the most hotly contested issues surrounding SBB is whether radiologists or surgeons should perform it. With appropriate training and experience, this procedure can certainly be accomplished by either. It is important to remember, however, that it is just as important for the mammograms to be interpreted carefully before a biopsy so that any additional lesions are identified. As noted above, when a patient is referred with an abnormal mammogram, the knowledge and training to recommend and interpret additional studies may obviate the need for biopsy of *any kind*. New regulations expected soon from the Food and Drug Administration will likely require anyone performing SBB or similar procedures to have devoted several months to mammographic training. Many surgeons have begun doing this procedure, but it is critical that they communicate with a reliable mammographic radiologist as they proceed. If surgeons perform

these procedures independently on the basis of screening mammogram findings, then they should have been fully trained, not only for the actual procedure but also in mammographic interpretation and work-up.

Conversely, if radiologists perform these procedures, they should not do so without surgical consultation. If they do, then they would need to be able to take full responsibility for physical examination of the patient, for informing the patient about the results and explaining the treatment options for malignancy. Generally, this would not be within the domain of the radiologist. It is unfair to a woman to inform her (perhaps by phone) that she has a malignant lesion and that she will need to seek a surgical referral from her primary physician. This approach may leave her "in limbo" without answers to her questions for an unacceptable period of time. Someone, preferably a surgeon with appropriate clinical experience, also needs to take responsibility for explaining and arranging appropriate follow-up for benign and "borderline" lesions. A good example of this problem is the finding of atypical ductal hyperplasia. Because sampling error can yield this result in patients who actually have cancer, this result should be followed by surgical excision of the entire lesion. One-third or more of these patients may have DCIS or invasive cancer on final pathology [3,14]. As noted earlier, radiographically guided biopsy procedures of all types should ideally be scheduled only after a balanced discussion and explanation by both radiologist and surgeon in a multidisciplinary setting. This approach is most likely to avoid unnecessary or extra procedures, it keeps the patient informed throughout the process, and it maintains the central role of surgeons in both the diagnosis and management of breast cancer. Because surgeons are the clinicians that have the greatest experience in the management of this disease, and surgery is still important for local control (and even cures some patients!), this role should not be diluted.

Sonographically guided needle biopsy is another approach that is rapidly being added to the choices for diagnosis, and is being performed by both surgeons and radiologists. Particularly when performed in the clinician's office or in radiology at the time of the first visit, this approach can minimize the anxiety-provoking delay that may be required for the scheduling of SBB or surgical biopsy. Clearly, however, delay of even several weeks has no real impact on clinical outcome. The ultrasound approach to core needle biopsy obviously is only useful for masses seen by ultrasound and is not useful for microcalcifications. Nevertheless, the use of this technique is rapidly increasing.

One of the newest techniques to enter this area is the advanced breast biopsy instrument, or ABBI. This is being heavily marketed to surgeons and to the public as a new way to diagnose and treat breast cancers, giving the impression to many that this is a *nonsurgical* approach.

In fact, this is an "open" surgical procedure, with a significant incision (up to 2 cm), potential for bleeding, and a scar. Simply put, the procedure is performed by "coring out" a cylinder of tissue centered on a localizing wire placed into the lesion under radiographic guidance. The technique is certainly innovative, but compared with SBB, it seems like too much of an operation for the biopsy of low to moderately suspicious abnormalities. For these lesions, a core needle biopsy obtained through a puncture site is much less invasive. If necessary, the mammatome instrument, which uses a rotating needle and suction, can remove all or most of a lesion through a single puncture wound. This instrument may be more accurate for certain lesions than simple cores, seems more appropriate for diagnosis than the ABBI and really is nonsurgical. As with SBB, the temptation to perform ABBI rather than repeating the mammogram in 6 months needs to be resisted for minimally suspicious lesions.

The other claim implied for the ABBI device is that it is a simpler and better way to excise occult lesions completely. This may prove to be true, but controlled trials comparing the adequacy of excision and the final cosmetic outcome with ABBI to the standard surgical approach for cancers are lacking. In fact, the device is not yet FDA-approved for definitive excision of cancers. Compared with careful placement of an incision directly over the tip of a well-placed localizing wire, followed by removal of the minimum amount of tissue completely surrounding the lesion, it is not clear that coring out a cylinder of tissue from the skin at the site of needle insertion will uniformly result in removal of less tissue. In fact, this approach resembles the use of incisions placed at the site of wire insertion and tunneling through the breast, an approach that is generally condemned by most experienced breast surgeons; such approaches actually "violate" other parts of the breast and remove more tissue than is necessary to achieve negative margins. Moreover, when using a surgical approach for excision of cancers, if the lesion appears close to one edge of the tissue, additional tissue can be excised at that edge to ensure a negative margin. To do this after an ABBI procedure reverts it to a standard surgical one. If a positive margin is found after an initial ABBI core procedure, it may be very difficult to determine which margin is involved, and reexcision of the entire field may be difficult to achieve with acceptable cosmesis. Finally, if an invasive cancer is removed in this way, a second surgical procedure will be required for axillary node dissection (at least according to current standards of care). Because general anesthetic is usually used for the latter, performing an ABBI procedure under local anesthesia before this procedure does not seem to have an advantage. It would seem less difficult to establish a cancer diagnosis of a highly suspicious mass by SBB core biopsy, and then to perform lumpectomy plus AND after needle localization

as a single procedure under general anesthesia. Certainly, ABBI may find a role in the increasingly complex set of choices for patients with different kinds of occult mammographic abnormalities, but it is not clear at this time what advantage it has over the established approaches described.

In conclusion, SBB is definitely a major advance in the diagnosis of occult breast abnormalities. It has the potential to reduce significantly the costs and discomfort of breast biopsy, and as outlined in Table I, has several clear-cut indications. However, regardless of the enthusiasm for its use, it needs to be incorporated rationally into the full selection of choices available, and the choice of diagnostic approach should be individualized for each patient. Ideally, the decision-making process will not take place in a vacuum by a radiologist or by a surgeon, but rather after joint discussion and consultation with breast surgeons and radiologists in a cooperative endeavor. This approach, rather than fighting over "turf," will certainly be most beneficial to patients.

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